

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed December 21, 2007 with respect to claim 11 have been fully considered but they are not persuasive. The examiner respectfully disagrees with the applicant's argument that Kjaer (*Regional Cerebral blood Flow During Light Sleep – a H_2^{15} O-PET Study*) analyzes the patient's brain in a state with external stimuli. True, in Kjaer, an external stimuli of a beep and an interview is performed, however this external stimuli was performed after the examination of the brain (image) was taken. The interview was to provide further information so that the stage 1 image that was taken can be further analyzed in view of the information about how the patient felt at that time.
2. The applicant also argues that it would not be obvious to use an MRI scan instead of a PET scan. The examiner respectfully disagrees. Although Langleben (US 2005/0154290 A1) discloses a method and system about whether an individual is being truthful or deceptive and with external stimulus, this does not change the fact that it is well known to use MRI to record cerebral blood flow, which is what the imaging system of Kjaer needs to do. For further reasons of why it is obvious to use MRI over PET look to Lovblad (*Silent fMRI demonstrates focal activation in REM sleep*) which says that PET has drawbacks and ideally brain function during the sleep-wake cycle should be assessed by methods such as using fMRI. Therefore the rejections for claims 11 and 12 still stand and are repeated below
3. Applicant's arguments with respect to the rest of the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 11 and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kjaer (*Regional cerebral blood flow during light sleep-a H₂¹⁵O-PET study*). Kjaer discloses a study in which signals of a patient's cerebral blood flow are recorded during a waking stage and a sleeping stage. Scans are taken while a patient is awake and then also when a patient was in stage-1 sleep. The signals from these two predetermined waking and sleeping state were then compared (taking a differential of change) to determine the portions of the brain that function in the sleeping stage versus the awake stage (pg. 202 col. 2 line 1-3, 5th full paragraph, last paragraph, pg. 203, col. 2 2nd paragraph under Discussion). An EEG is also recorded during the entire experiment (pg. 202 col. 1 last sentence of paragraph 4). Although in the study of Kjaer, a PET scan was used, it would be obvious to one skilled in the art to use any type of imaging system that can record cerebral blood flow such as an MRI system (see paragraph 0009 of US 2005/0154290 A1 to Langleben).

6. **Claims 1, 3-8, 11 and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lovblad (*Silent functional magnetic resonance imaging demonstrates focal activation in rapid eye movement sleep*). Lovblad discloses performing fMRI to determining brain functions during

human sleep. A biosignal detection means such as an EEG, or a polysomnogram, is used to identify the sleep stages of the volunteers. The detection of the EEG signal and the MRI signal must be performed alternately as the MRI signal causes a radiofrequency interference on the EEG signal rendering the EEG uninterpretable and undetectable (3rd paragraph in Methods, 2nd paragraph in Results). Cardiac gating was also used to minimize artifacts in the brain image (2nd paragraph in Methods). The fMRI imaging was performed over the whole sleep period (which includes a wake stage). The changes in pixel intensity over time and over the sleep stages were analyzed and compared to determine which areas of the brain is functioning in each of the respective sleeping states in comparison to the other stages (2nd and 3rd paragraph of Results, 1st paragraph of Discussion). Although Lovblad does not explicitly state taking a differential of change in the MRI signal strength, the analyzing of the changes in pixel intensity correlates directly with the changes of MRI signal strength as the darker the pixel the weaker the signal strength so it would therefore be obvious to directly use a differential of change in the signal strength versus the pixel intensity.

7. **Claim 9** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lovblad as applied to claim 6 above, and further in view of Cohen (WO 02/13689 A2). Cohen discloses a method for reducing a contamination of an electric signal. To do this the estimated contaminating signal, which could be a heartbeat noise, is subtracted from the digital signal, such as an EEG signal (summary of the invention). It would be obvious to one with ordinary skill in the art at the time of the invention to combine Cohen with Lovblad in order to further the utility of Lovblad to obtain clear EEG signals.

8. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lovblad in view of Cohen as applied to claim 9 above, and further in view of Humphrey (US 6,171,239 B1).

Humphrey discloses reading neural signals using EEGs. Humphrey also discloses being able to determine a frequency of occurrence of neural spikes, which can be easily outputted on a display (col. 11 line 39-41). It would be obvious to one with ordinary skill in the art at the time of the invention to combine Humphrey with Lovblad and Cohen as once EEG signals are being read it would be obvious and easy to keep track of a frequency of occurrence and display such information.

9. **Claims 13, 15, 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lovblad in view of Cohen in view of Humphrey as applied to claim 10 above. Lovblad discloses that the event identification uses EEG, sleep spindles, and K-complexes to determine the stages of sleep (4th paragraph of Methods) and determines that the left thalamus of the brain functions during REM sleep (1st paragraph of Discussion).

10. **Claim 14** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lovblad in view of Cohen in view of Humphrey as applied to claim 10 above, and further in view of Ohkawa (US 6,348,485 B1). Lovblad discloses using EEG to determine the stages of sleep, but does not explicitly disclose how the EEG relates to the stages of sleep. It would be obvious to use any well known method of converting EEG signals into the stages of sleep as disclosed by Ohkawa.

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Ohkawa discloses that a well known method of determining stages of sleep (wake, 1, 2, 3, 4, and REM) is using FFT on EEG (col. 10 line 8-15).

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

12. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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3737

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